

Claims

1. An aerosol formulation comprising a biodegradable
microsphere of average diameter of from 0.5 to 5 μ m comprising a
5 non-living reagent that produces a protective immune response in
a mammal to whom it is administered.
2. A formulation according to claim 1 wherein the said non-
living reagent is antigenic polypeptide or a nucleic acid
10 sequences which may encode such a polypeptide.
3. A formulation according to claim 2 wherein the said non-
living reagent is a sub-unit vaccine.
- 15 4. A formulation according to any one of the preceding claims
wherein the said non-living reagent is diphtheria toxoid, tetanus
toxoid, *Botulinum* toxin FHC, *Bacillus anthracis* protective
antigen (PA) or a polypeptide which is capable of generating a
protective immune response against *Yersinia pestis*.
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5. A formulation according to claim 4 wherein the non-living
reagent is the V antigen of *Y. pestis* or an immunologically
active fragment thereof or a variant of these, or the F1 antigen
of *Y. pestis* or an immunologically active fragment thereof or a
25 variant of these, or a combination of these.
6. A formulation according to any one of the preceding claims
wherein the microspheres have an average diameter of less than
3 μ m.
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7. A formulation according to claim 6 wherein the
microcapsules have an average diameter of between 1 and 1.5 μ m.
8. A formulation according to any one of the preceding claims
35 wherein the microsphere comprise a biodegradable polyester.

9. A formulation according to claim 8 wherein the polyester comprisescomprise Poly-lactide (PL).
10. A formulation according to any one of the preceding claims
5 wherein the microcapsules are lyophilised.
11. A formulation according to any one of the preceding claims wherein the non-living reagent is encapsulated within the microspheres.
- 10 12. A formulation according to any one of the preceding claims which further comprises the non-living reagent in free form.
13. A formulation according to claim 12 wherein the ratio of
15 the amounts of the free reagent to the reagent associated with the microspheres is in the range of from 1:20 to 2:1.
14. A formulation according to any one of the preceding claims in unit dosage form.
- 20 15. A nebulizer or inhaler comprising a formulation according to any one of the preceding claims.
16. The use of biodegradable microspheres having an average
25 diameter of from 0.5 to 5 μ m and comprising a non-living reagent that produces a protective immune response in a mammal to whom it is administered, in the preparation of a vaccine for administration as an aerosol.
- 30 17. A method of producing a protective immune response in a mammal in need thereof, said method comprising administering to the lung of said mammal, a protective amount of an aerosol formulation according to any one of claims 1 to 14.